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No. 07-1537

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SUPREME COURT

In The

Supreme Court of the United States

STRYKER CORPORATION,

Petitioner,

v.

TRIMED, INCORPORATED,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether Petitioner has presented compelling reasons to grant the Petition, where the Federal Circuit did not invoke 35 U.S.C. §112, ¶6 in interpreting a claim term that recites structure which performs the claimed function.

2. Whether Petitioner has presented compelling reasons to grant the Petition, where the Federal Circuit used the patent's prosecution to interpret a claim term differently from the Petitioner.

CORPORATE DISCLOSURE STATEMENT PURSUANT TO SUPREME COURT RULE 29.6

Respondent TriMed, Incorporated does not have a parent corporation and there is no publicly held company that owns 10% or more of its stock.

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INTRODUCTION

This is a patent infringement suit, and there are two issues presented. First, whether Title 35 U.S.C. §112, ¶6 must always be invoked if a patent's claim includes the word "means." Second, whether the Federal Circuit properly interpreted the file history of the patent-in-suit.

Petitioner asks this Court to review the Federal Circuit's holding wherein the claim uses the term "means," but 35 U.S.C. §112, ¶6 was not invoked since there was sufficient structure recited in the claim to perform the claimed function. Petitioner argues that not invoking 35 U.S.C. §112, ¶6 to a claim term that uses the term "means" is a "judicially-created" exception to statutory mandate of 35 U.S.C. §112, ¶6, however, Petitioner's reading of the statute is incorrect. The statute clearly states that §112, ¶6 is invoked when structure is not recited in a claim. The Federal Circuit held that sufficient structure was recited, hence, §112, ¶6 need not be invoked. There was no err in the Federal Circuit's statutory construction of 35 U.S.C. §112, ¶6.

Petitioner incorrectly asserts that "the Federal Circuit has eroded the public notice function" of a prosecution history by "disregarding" it in its claim interpretation. The Federal Circuit discussed the prosecution history of the patent-in-suit, and used it to interpret the claim term in dispute. Petitioner's Brief, pp. 8a-10a. Petitioner simply disagrees with

the Federal Circuit's claim interpretation and the impact the file history had on that interpretation.

STATEMENT OF THE CASE

I. The Parties

TriMed, Incorporated ("TriMed") is a corporation located in California that manufactures and sells orthopedic implant products to hospitals and surgical centers located throughout the world. TriMed was started by orthopedic surgeon Dr. Robert Medoff and two partners in 1997 and now has over 200 sales representatives. Dr. Medoff is the inventor of the U.S. Patent No. 5,931,839 (the '839 Patent) which has been assigned to TriMed. Stryker is a Michigan corporation also in the field of orthopedic implant products. The patent and infringing device at issue pertain to a wrist fixation implant.

II. The Technology

A wrist fracture, also known as a distal radius fracture, results in the bone breaking into one or more "fractured bone fragments" and a "stable bone fragment." The fractured fragment is the small distal part of the bone toward the hand that is broken away from the remaining stable fragment which extends proximally toward the forearm.

One product used by surgeons to repair wrist fractures consists of a thick plate and screws wherein

a surgeon opens the skin to expose the fracture and position a thick metal plate across the fracture. The surgeon rotates a screw into the stable fragment until it is secured therein. To secure the fractured fragment to the thick plate, the surgeon rotates a screw into the fractured fragment. As the screw is tightened, the screw head limits the axial movement of the screw going into the bone, however, the continued rotation of the screw, which is required to fully secure the fractured fragment, causes the fractured fragment tc migrate up and against the plate. Thus, both fractured fragments are secured to the plate by way of two separate screws. This procedure has significant drawbacks.

First, in order to capture the fractured fragment and lock it to the plate, the screw must have thick threads. This requires the surgeon to make a large hole in the fractured fragment, often causing secondary fragmenting of the fractured fragment. Also, if the bone is small or osteoporotic, which is often the case, the screw threads simply cannot capture the fractured fragment. Another significant problem of this method occurs as the screw is tightened and the fractured fragment is forced to migrate up and against the plate. This causes an undesirable compressive force across the fracture which can cause significant problems such as the fractured fragment shattering.

To overcome these problems, Dr. Medoff conceived and developed the "Pin Plate," which is the '839 patented invention. The Pin Plate was a radical

breakthrough which greatly simplified the surgical process, and most importantly, significantly improved recovery with better long-term effects. In the orthopedic industry, TriMed's patented Pin Plate is considered revolutionary. Certain figures of the '839 Patent follow:

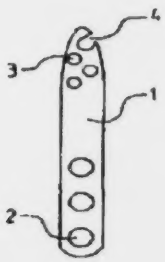

Fig. 1

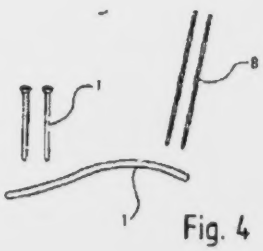

Fig. 4

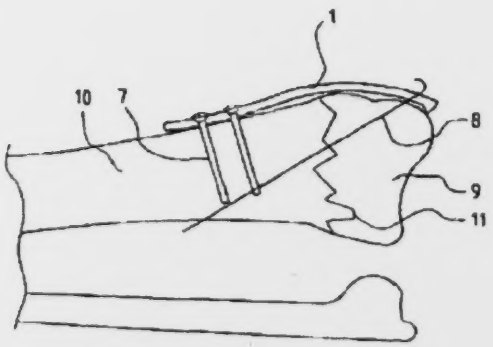

Fig. 5

Looking at Figure 1, a plate 1 has screw holes 2 and pin holes 3. Fig. 4 illustrates the pins 8, screws 7 and side view of the plate 1, and Figure 5 is a top view of a distal portion of the wrist bone (the "distal radius") with an implanted Pin Plate showing the

stable fragment 10, fractured fragment 9 and the line of fracture 11. (The forearm is to the left of figure 5 and the hand is to the right of figure 5.) For illustrative purposes, to implant a Pin Plate, Figure 5 shows a thin pin 8 (also called a "k-wire") that a surgeon slides into the fractured fragment 9 so the pin 8 crosses the fracture 11. One end of the pin 8 terminates within the stable fragment 10, and the other end of the pin is extended beyond the fractured fragment 9 and across the fracture 11.

A thin plate 1 is then slid over the exposed end of the pin 8 and is positioned on the bone so it crosses the fracture 11, with the part of the plate having screw holes 2 positioned on the stable fragment 10 and the part of the plate having pin holes 3 positioned on the fractured fragment 9. Screws 7 are inserted though screw holes 2 in the plate 1 and into the stable fragment 10. The exposed end of the pin 8 is cut and the remaining exposed end is bent to form a "J" hook, so the end of the pin can be inserted into another pin hole 3 in the plate 1 or can lie on the plate surface.

The key to the Pin Plate is this: (1) a thin pin captures and fixates the fractured fragment, and (2) the holes in the plate allow the pin to slide axially which prevents compression along the fracture while at the same time stabilizes the pin by preventing the end of the pin from twisting, bending or otherwise moving across the top surface of the plate (the plane of the plate). That is, (1) the interior of the hole allows the pin to axially slide therein and through the

fractured bone fragment, across the fracture and into the stable bone fragment, thereby preventing compression across fracture (because the fragmented bone fragment is not pulled-up to the plate during fastening) and (2) the circumferential surface of the hole stabilizes the near end of the pin against displacement in the plane of the plate; i.e., it forms a boundary which the near end of the pin cannot cross, thus preventing twisting, bending, or other movement across the top surface of the plate.

Thus, using the patented Pin Plate, the thin pin fixates the fractured fragment. The sole function of the plate is to provide holes to allow the pin to axially slide (to prevent compression) and to stabilize the pin from movement across the plane of the plate.

The patented Pin Plate solved two significant problems: (1) because thin pins (as compared to thick screws) are used, additional fracturing of the fractured fragment does not occur when capturing the small or sometimes osteoporotic fragments; and (2) compression across the fracture is prevented since the holes allow the pins – which are the fixation tools – to slide axially.

III. The Decisions At The Lower Courts

The District Court for the Central District of California granted summary judgment for noninfringement without a written opinion. The District Court entered judgment for Petitioner and merely

signed Petitioner's Statements of Fact and Law, though highly disputed, as the Court's own.

The Court of Appeals for the Federal Circuit ("the Federal Circuit") reversed the District Court's decision, and in so doing, interpreted the only disputed claim term. Contrary to Petitioner's argument, the Federal Circuit interpreted the relevant statute, 35 U.S.C. §112, ¶6, exactly as the statute is written. The statute states that an element in a claim may be expressed as a "means" for performing a specified function *without the recital of structure*, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. The Federal Circuit held that although the claim term contains the word "means," it did not invoke 35 U.S.C. §112, ¶6 because there was sufficient structure in the claim describing the means. Petitioner's Brief, p. 7a.

The Federal Circuit stated that with a side-by-side comparison between Figure 5 of the '839 Patent and Stryker's accused product, "it is hard to imagine any significant structural differences between the two." (Petitioner's Brief, p. 11a)

REASONS FOR DENYING THE PETITION

The decision by the Federal Circuit below does not conflict with a decision of this Court, previous decisions by the Federal Circuit, nor the statutory language of 35 U.S.C. §112, ¶6.

Contrary to the issues raised in Petitioner's Statement of the Case, the Federal Circuit's decision did not create a "judicial exception" to 35 U.S.C. §112, ¶6. Title 35 U.S.C. §112, ¶6 is invoked when a claim limitation is written in means-plus-function language without the recitation of structure. The Federal Circuit held that the claim limitation at issue contains sufficient structure, thus, 35 U.S.C. §112, ¶6 was properly not invoked.

Further, the Federal Circuit did not "simply dismiss a patent's prosecution history," rather it expressly considered the prosecution history in interpreting the claim language. Petitioner's Brief, pp. 8a-10a.

Petitioner's Petition for Writ of Certiorari should be denied since it has not carried its burden of demonstrating any compelling reasons for the Petition to be granted. *See* Sup.Ct.R. 10.

I. The Federal Circuit Correctly Interpreted The Last Element Of Claim 1 By Not Invoking 35 U.S.C. §112, ¶6

Title 35 U.S.C. §112, ¶6 states that when an element is written in a means-plus-function format without structure to perform the function, the structure is limited to that disclosed in the specification and equivalents thereof:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function *without the recital of*

> *structure, material, or acts in support thereof*, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. 35 U.S.C. §112, ¶6 (emphasis added)

Thus, if the claim recites structure, with or without the word "means," that element is not a means-plus-function element under 35 U.S.C. §112, ¶6. This clear reading of the statute has been the established law. *Cross Med. Prod., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1304 (Fed. Cir. 2005) ("anchor seat means"); *TI Automotive Sys., Inc. v. VDO North Am., LLC*, 375 F.3d 1126, 1135 (Fed. Cir. 2004) ("pumping means"); *Envirco Corp. v. Clestra Cleanroom, Inc.*, 209 F.3d 1360 (Fed. Cir. 2000) ("baffle means" was not a means-plus-function); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed. Cir. 1996) ("perforation means").

The Federal Circuit first addressed this issue in *York Products, Inc. v. Central Tractor Farm & Family Center*, 99 F.3d 1568, 1574 (Fed. Cir. 1996). In addressing 35 U.S.C. §112, ¶6 the court held that if the claim element uses the word "means" but also recites the structure to perform the means, the element is not subject to 35 U.S.C. §112, ¶6 because "the express structural limits of the claim language limit its scope." That is, because the claim itself limits the structure, and does not cover all conceivable structures, it only covers the structure expressly stated in the claim. Thus, 35 U.S.C. §112, ¶6 does not apply.

The Federal Circuit's application is exactly how 35 U.S.C. §112, ¶6 is written. Title 35 U.S.C. §112, ¶6 expressly requires the lack of structure, i.e., "means," to perform the claimed function. If the element recites the precise structure that performs the claimed function, §112, ¶6 does not apply.

The Federal Circuit's application of 35 U.S.C. §112, ¶6 is wholly consistent with policy of the enactment of the statue which was caused by *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 9-12 (1946). *Halliburton Oil* held that claims including "means-plus-function" elements that did not recite structure to perform the function were invalid for being too broad and vague. Thus, 35 U.S.C. §112, ¶6 was enacted to limit "means-plus-function" elements that did not recite structure in the claim. However, if a claim element recites the precise structure that performs the function – whether or not it also includes the word "means" – it is *not* too broad and vague, as the recited structure in the claim limits the claim, and the statute is not required to limit the claims.

In the present case, the '839 Patent has one independent claim, which states the following, with the last paragraph (in bold) being in issue:

> An implantable device for fixation of at least one fractured bone fragment to a stable bone fragment, said implantable device comprising:

an implantable plate having opposite end portions, fastening means for securing one end portion of said plate to stable bone,

at least one fixation pin for penetrating said at least one fractured bone fragment, and traversing a fracture for entering the stable bone fragment and for being secured therein at a stable fixation site at a far end of said fixation pin,

the opposite, near end of said pin being adapted for extending from the fractured bone fragment,

said near end of said pin being engageable in one of a plurality of holes in the other end portion of the plate,

said holes in said plate providing means for allowing the pin to slide axially therein but preventing compression across the fracture, and stabilizing said near end of the pin against displacement in the plane of the plate.

The claim element at issue is "*said holes in said plate providing means* for allowing the pin to slide axially therein but preventing compression across the fracture, and stabilizing said near end of the pin against displacement in the plane of the plate."

The holes in the plate, as expressly stated in the claim element, is the structure that performs the function – the hole (the interior portion) allows the pins to slide axially thus preventing compression across the fracture, and the circumferential surface

forms the boundary of the hole and stabilizes the pin against displacement in the plane of the plate. Because the holes are the structure and it is expressly present in the claim, there is structure in the claimed element, and thus, the element is not governed by 35 U.S.C. §112, ¶6.

The opinion by the Federal Circuit is entirely consistent with the Statute. In applying the precise language of 35 U.S.C. §112, ¶6, the Federal Circuit held that the claim element recites the structure, and is thus not governed by 35 U.S.C. §112, ¶6: "The claim language makes clear that the structure for performing these functions is the holes themselves." (Petitioner's Brief, p. 7a)

Petitioner wrongly attacks the Federal Circuit by stating that it "created a judicial exception," "engaged in an incorrect application," and has "created a loophole." Not only is Petitioner incorrect, to the contrary, the Federal Circuit has applied the statue *exactly* as written.

Whether intentionally or by oversight, Petitioner's fundamental misunderstanding of 35 U.S.C. §112, ¶6 is most evident in its statement at page 3 of its brief. Petitioner criticizes the Federal Circuit for not applying "the claim construction mandate of 35 U.S.C. §112, ¶6 to ***all*** claim elements which invoke 'means' language." Petitioner's argument that 35 U.S.C. §112, ¶6 applies to all claim elements that use the term "means" does not comport with the plain words of the statute. Petitioner refuses to acknowledge that 35

U.S.C. §112, ¶6 is only invoked when there is no recital of structure in the claim. Tellingly, instead of quoting the entire statute, Petitioner selectively leaves out the statute's key words "without the recital of structure." Petitioner's misleading quote of the statute is as follows:

> Under the statute, an applicant is allowed to claim his or her invention "as a means or step for performing a specified function," but if the applicant does so "such claim shall be construed to cover the corresponding structure, material or acts described in the specification or equivalents thereof." (Petitioner's Brief, p. 18)

However, the actual statute states:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function *without the recital of structure, material, or acts in support thereof*, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. 35 U.S.C. §112, ¶6 (emphasis added)

Petitioner's argument rings hollow when exposed to the actual words of the statute. According to Petitioner, the words "without the recital of structure" are meaningless and should be disregarded. This is plainly a misinterpretation of the law.

II. The Prosecution History Is Consistent With The Interpreted Claim and Was Not "Disregarded"

Stryker repeatedly states that TriMed and the Patent Office struck an agreement that the claim limitation at issue is a means-plus-function limitation. (Petitioner Brief, pp. 4, 10, 30) This is incorrect and misrepresents the events before the Patent Office. Specifically, on August 17, 1998, Dr. Medoff and his attorney demonstrated the invention to the examiner in person and discussed Claim 11, which became Claim 1 of the '839 Patent. The Interview Summary states the following:

> Discussion centered around focusing on the structural difference between the applicant's pin/plate attachment and the traditional screw/plate attachment . . . *The configuration of the present device allows the pin to be attached to the plate in a sliding manner that prevents compression across the fracture.* Agreement was reached that *expression of this feature in a means plus function format* and better defining the holes of the plate would distinguish over the prior art of record. Petitioner's Brief, p. SA-7 (emphasis added)

"This feature" referred to by the examiner is that of *attaching the pin and plate in a sliding manner so as to prevent compression across the fracture*, and if it had been written in means-plus-function format, would have distinguished the invention over the prior art of a thick plate with screws.

In the following amendment, TriMed went beyond drafting this limitation in means-plus-function format. Specifically, TriMed did *not* merely recite "means for allowing the pin to slide relative to the plate and prevent compression across the fracture." Rather, TriMed amended the claim by adding the exact structure of "this feature" – the holes in the plate – that perform the claimed functions. It added the entire last paragraph of the claim, which is the limitation at issue:

> *said holes in said plate providing means for allowing the pin to slide axially therein but preventing compression across the fracture, and stabilizing said near end of the pin against displacement in the plane of the plate.* (Petitioner's Brief, SA-9 and SA-6, col. 6, lns. 29-32)

Thus, TriMed, in amending the claim, did more than it had to – it limited its claim by reciting the specific structure as a limitation. It claimed "holes" as the means to perform the recited function instead of stating merely "means" without any structure. Indicative that the holes provide the necessary structure is the fact that the presence of the word "means" adds absolutely nothing to the claim, and removing the word "means" has no effect whatsoever. *Cole*, 102 F.3d 524, 531. ("Here, the claim drafter's perfunctory addition of the word "means" did nothing to diminish the precise structural character of this element. It definitely did not . . . somehow magically transform

this element into a §112, ¶6 'means-plus-function' element.")

In the "Remarks" section following the aforementioned amendments, TriMed explained that the near end of the pin (which protrudes from the fracture) engages *the hole* in the plate, wherein the hole allows the pin to slide axially therein and stabilizes the pin again migration while preventing compression across the fracture. Petitioner's Brief, SA-11-SA-12.

Thus, TriMed amended the claim by adding the limitation of defining the relationship between the pin, the plate, and the holes in the plate, where the pin fixates the fracture and (1) does not cause compression because the holes in the plate allow the pin to slide axially through the fractured and stable fragment, and (2) stabilizes the end of the pin against displacement in the plane of the plate. As discussed above, the first function is performed by the interior of the hole which provides an area for the pin to axially slide, and the second function is performed by the circumferential surface of the hole which prevents the near end of the pin from moving across the hole, i.e., lateral to the plate. This relationship excluded the prior art of plates and screws wherein the plate fixates the fracture and the tightening of the screws into the plate compress the fracture.

III. Even Under 35 U.S.C. §112, ¶6, The Structure Disclosed in the '839 Specification Includes Plain Holes

Even if the claimed element is a "means-plus-function" element and subject to 35 U.S.C. §112, ¶6, TriMed is entitled to protection covering the corresponding structure described in the specification, as well as all equivalents thereof. 35 U.S.C. §112, ¶6; *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1375 (Fed. Cir. 2003).

The '839 specification expressly states that one of the means to perform the function of allowing the pins to slide axially *are holes*. The first example in the '839 specification explains in detail how the pins 8 pass through the holes 3 in the plate and can be bent over the plate to prevent migration of the pin. (Petitioner's Brief, SA-5, SA-6, col. 4:56-col. 5:3) It also states that "the plate has distal holes 3 through which the pin 8 is passed; additionally, these holes 3 *may or may not* have slots 4." (Petitioner's Brief, SA-6, col. 5:1-3) Moreover, this is exactly what is shown in Figure 5 – the structure to perform the claimed function is the holes 3. The opinion of the Federal Circuit addressed this and stated the same: "Even if we were to construe this as a §112 ¶6 claim, the specification discloses an embodiment that has precisely the same structure that is found in the accused devices." Petitioner's Brief, 7a-8a.

Stryker argues that the specification of the '839 Patent does not disclose a plate with holes and nothing

more to perform the claimed functions. (Petitioner's Brief, pp. 8, 11 and 22) Stryker states that the '839 specification lists six different methods of locking the pin to the plate, including a slot in the plate, threaded holes with threaded pins, a locking nut, an undersized hole with a cut, a slotted hole joined with an undersized hole, or a threaded or slotted stud.

Stryker conveniently fails to state that these are all *alternative embodiments* to the very first embodiment which is simply to use a plain hole as described above. In the first embodiment the use of a slot in the plate is described as optional; the '839 specification explains that the pins 8 pass through the holes 3 in the plate *which may or may not have slots*:

> The plate has distal holes 3 through which the pin 8 is passed; additionally, *these holes may or may not have slots*. Petitioner's Brief, SA-6, col. 5, lns. 1-3.

The '839 specification continues to list examples of alternative ways to stabilize the near end (the protruding end) of the pin to the plate, the first method being bending the pin over the surface of the plate:

> The fixation of the pins 8 at the pin plate 1 is accomplished in different ways in different embodiments of the invention. *In one embodiment the pins 8 are bent over the superficial surface of the plate 1 as stated above.* Petitioner's Brief, SA-6, col. 5, lns. 22-25.

Thus, the first embodiment *does not require* slots. A pin and a plate with holes are all that are required

to perform the functions of (1) allowing the pin to slide axially in the plate and (2) stabilizing the near end of the pin against displacement in the plane of the plate. No "locking structure" is required to perform the functions of allowing the axial sliding and preventing the displacement of the pin in the plane of the plate.

The other disclosed ways of stabilizing the pin to the plate include threaded pins and threaded holes, pins with locking nuts, holes with slots, and threaded studs. (Petitioner's Brief, SA-6, col. 5, lns. 25-51) However, Stryker ignores the very first embodiment which discloses a plain hole – with or without a slot – and a pin where the pin was bent over the hole. That is it – just a pin and a hole.

Stryker's argument that holes and "something more" are required in order to "lock" the pin to the plate is contrary to the specification and arguments made to the examiner during prosecution of the patent.

CONCLUSION

Petitioner has not established any compelling reasons for this Court to grant the Petition. Therefore, Respondent respectfully request that the Petition be denied.

Respectfully submitted,

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